June 17, 2022

Arrow Intl., Inc.
Karen Provencher
Senior Regulatory Affairs Specialist
9 Plymouth St.
Everett, Massachusetts 02149

Re: K060309
Trade/Device Name: Autocat Intra-Aortic Balloon Pump Series
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic balloon and control system
Regulatory Class: Class II
Product Code: DSP

Dear Karen Provencher:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 6, 2005. Specifically, FDA is updating this SE Letter to reflect an administrative correction corresponding to the reclassification of intra-aortic balloon and control system (IABP) devices when indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure, a preamendments class III device, into class II (special controls), as detailed in the final order published on December 20, 2019 (see here for more information: https://www.federalregister.gov/documents/2013/12/30/2013-31218/cardiovascular-devices-reclassification-of-intra-aortic-balloon-and-control-systems-for-acute#:~:text=The%20Food%20and%20Drug%20Administration%20(FDA)%20is%20issuing%20a%20final,(special%20controls)%2C%20and%20to). In addition, IABP devices indicated for septic shock or pulsatile flow generation will remain Class III devices and would not be appropriate for the premarket notification pathway(510(k)), instead requiring a premarket approval (PMA).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Alejandra Cambonchi, OHT2: Office of Cardiovascular Devices, 301-796-0552, Alejandra.Cambonchi@fda.hhs.gov.

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

Arrow International, Inc.
c/o Ms. Karen Provencher
Senior Regulatory Affairs Specialist
9 Plymouth Street
Everett, MA 02149

Re: K060309
Arrow AutoCAT Intra-Aortic Balloon Pump (IABP) Series
Regulation Number: 21 CFR 870.3535
Regulation Name: Balloon, Intra-Aortic and Control System
Regulatory Class: Class III
Product Code: DSP
Dated: March 17, 2006
Received: March 23, 2006

Dear Ms. Provencher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K060309

Device Name
AutoCAT Intra-Aortic Balloon Pump Series

Indications for Use *(Describe)*
The AutoCAT Intra-Aortic Balloon Pump Series is clinically indicated for the following conditions:
a. Acute Coronary Syndrome
b. Cardiac and Non-Cardiac Surgery
c. Complications of Heart Failure

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Arrow International, Inc

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510(k) Summary K060309

AutoCAT Series IABP Series
Date Prepared: February 3, 2006
Date Summary Updated: July 28, 2015

A. **Submitter's Name:**

Arrow International, Inc.
9 Plymouth Street,
Everett, MA 02149

Updated Correspondent Address:

Fusun Tufan
Senior Regulatory Affairs Manager
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16 Elizabeth Drive,
Chelmsford, MA 01824
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B. Company Contact

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C. **Device Name**

Trade Name: AutoCAT Intra-Aortic Balloon Pump Series
Common Name: Intra-Aortic Balloon Pump (IABP)
Classification Name: Intra-Aortic Balloon and Control System

D. **Predicate Devices**

Arrow International AutoCAT Series IABP System represents the integration of four Arrow IABP technologies which is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution:

- AutoCAT, cleared in K983866, (1/6/00)
- ACAT 1, cleared in K965209, (1/23/98)
- ACAT 2, cleared in K002256, (5/3/01)
- FOS / FOMS IAB Black Box, cleared in K021462, (6/6/02)

E. **Description of Device**

The Intra-Aortic Balloon Pump (IABP) provides cardiac assist therapy. The IABP provides temporary support to patients with impaired left ventricular function through the therapeutic method referred to as counterpulsation. Counterpulsation increases coronary and systemic profusion, decreasing after load (myocardial work) and decreasing preload.

The AutoCAT Series IABP System utilizes computer technology to select and maintain precise

IAB inflation and deflation timing and triggering based on current physiological data from the patient. The system offers two modes of operation, the Autopilot mode, where functions are automatically selected and controlled by the IABP and the Operator mode where the user has control over settings and selections.

F. Indications for Use

The AutoCAT Intra-Aortic Balloon Pump Series is clinically indicated for the following conditions:

a. Acute Coronary Syndrome
b. Cardiac and Non-Cardiac Surgery
c. Complications of Heart Failure

G. Comparison of Technological Characteristics

The modified Software V2.22 features the modifications to the following- Clarification / Modification to Pre-set Start-up Settings, General Improvements in AutoPilot Timing, Modifications to AP Zero and Calibration Function, Improvements in AutoPilot Signal Switching & Selection, General Improvements in Triggering, Improved Purge Cycle & Helium Refill Function, Recognition of IAB Connector Volumes, Improved Noise Recognition and Handling, Modifications to Arrhythmia Timing Function, Alarm Handling Improvements, Additions to Help Text, Activation of Modem Function, Regular Output of RS232

H. Summary Performance Data

The AutoCAT IABP Series with modified software meets all the same performance standards of the unmodified device including the following:

1. FDA Guidance: "Guidance for the Preparation and Content of Applications to the Food and Drug Administration for Determining the Equivalence of Intra-Aortic Balloon Catheters and Consoles under the 510(k} Regulations - Preliminary Draft, December 8,1993
2. FDA Guidance: "General Principles of Software Validation -Final Guidance' January 11, 2002
3. FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Final Guidance' May 11, 2005
4. IEC 60601-1-4:1997: Medical Electrical Equipment- General Requirements for Safety- Collateral Standard: Programmable Electrical Medical Systems
5. EN 55024:1998: Information Technology Equipment- Immunity Characteristics
6. EN 55022:1998: Information Technology Equipment- Radio Disturbance Characteristics Limits and Methods of Measurement